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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,156	03/17/2004	Scott R. Baerson	11898.0019.DVUS02 (MOBS:0)	8051
23369	7590	03/02/2006	EXAMINER	
HOWREY LLP C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE, SUITE 200 FALLS CHURCH, VA 22042-7195			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,156

Applicant(s)

BAERSON ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4,5,24 and 25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/17/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The first line of the specification as amended in the preliminary amendment filed 17 March 2004 is objected to because the parental application 09/800,130 has issued as a US Patent, this line should be amended to reflect this.

Appropriate correction is required.

Claim Objections

2. Claim 5 is objected to because of the following informalities: "A DNA" should read -- The DNA -- because it is further limiting the invention of claim 4. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

4. Claims 4 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,803,501 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claimed in the issued US patent renders obvious the genus of isolated DNA molecules encompassed by the instant claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4, 5, 24 and 25 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated DNA molecule that encodes a naturally occurring glyphosate resistant plant-derived EPSPS enzyme, wherein the glyphosate resistant EPSPS enzyme has a K_m for phosphoenolpyruvate (PEP) of less than 10 μ M, and wherein said naturally occurring glyphosate resistant EPSPS enzyme is modified by a substitution or a deletion of at least one amino acid in a catalytic domain. Applicant also claims an isolated DNA molecule comprising the promoter region or transit peptide

coding region located 5' to a DNA molecule that encodes a naturally occurring glyphosate resistant EPSPS enzyme derived from *Eleusine sp.*

Applicant describes a naturally occurring mutant DNA isolated from an *Eleusine indica* encoding a glyphosate resistant EPSPS enzyme having a serine substituted for a proline at position 107 in SEQ ID NO: 7.

Applicant does not describe other naturally occurring mutant DNAs isolated from an *Eleusine sp* encoding a glyphosate resistant EPSPS enzyme, nor does Applicant describe the promoter region or the chloroplast transit peptide coding region of the exemplified *Eleusine indica* isolated DNA.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed.

As directed to Applicant's claim of any isolated DNA that encodes a naturally occurring glyphosate resistant plant-derived EPSPS enzyme, wherein the glyphosate resistant EPSPS enzyme has a K_m for phosphoenolpyruvate (PEP) of less than 10 μ M; see *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural

features common to the members of the genus, which features constitute a substantial portion of the genus. The Examiner notes that there are at least 15 recognized species in the genus *Eleusine*.

As directed to Applicant's claim of an isolated DNA that comprises the promoter region or transit peptide coding region located 5' to a DNA molecule that encodes a naturally occurring glyphosate resistant EPSPS enzyme derived from *Eleusine sp.*; See *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself". See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

7. Claims 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule that encodes the naturally occurring glyphosate resistant plant-derived EPSPS enzyme of SEQ ID NO: 7, wherein the glyphosate resistant EPSPS enzyme has a K_m for phosphoenolpyruvate (PEP) of less than 10 μ M, and wherein said naturally occurring glyphosate resistant

EPSPS enzyme is modified by a substitution selected from the group consisting of glycine to alanine 102 and threonine to isoleucine 103 of SEQ ID NO:7, does not reasonably provide enablement for any isolated DNA molecule that encodes any naturally occurring glyphosate resistant plant-derived EPSPS enzyme, wherein the glyphosate resistant EPSPS enzyme has a K_m for phosphoenolpyruvate (PEP) of less than $10\mu\text{M}$, and wherein said naturally occurring glyphosate resistant EPSPS enzyme is modified by any substitution or a deletion of at least one amino acid in a catalytic domain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims an isolated DNA molecule that encodes a naturally occurring glyphosate resistant plant-derived EPSPS enzyme, wherein the glyphosate resistant EPSPS enzyme has a K_m for phosphoenolpyruvate (PEP) of less than $10\mu\text{M}$, and wherein said naturally occurring glyphosate resistant EPSPS enzyme is modified by a substitution or a deletion of at least one amino acid in a catalytic domain.

Applicant teaches a naturally occurring mutant DNA isolated from an *Eleusine indica* encoding a glyphosate resistant EPSPS enzyme having a serine substituted for a proline at position 107 in SEQ ID NO: 7.

Applicant does not teach other naturally occurring mutant DNAs isolated from an *Eleusine sp* encoding a glyphosate resistant EPSPS enzymes.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be

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necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides limited guidance on how to make any isolated DNA molecule that encodes any naturally occurring glyphosate resistant plant-derived EPSPS enzyme, wherein the glyphosate resistant EPSPS enzyme has a K_m for phosphoenolpyruvate (PEP) of less than $10\mu\text{M}$, and wherein said naturally occurring glyphosate resistant EPSPS enzyme is modified by any substitution or a deletion of at least one amino acid in a catalytic domain as broadly claimed. Naturally occurring mutations are infrequent and random events and it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to identify other DNA molecules encoding such an EPSPS enzyme as broadly claimed. It would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of plant species to identify and isolate other DNA molecules that encode a naturally occurring glyphosate resistant EPSPS enzyme that has a K_m for PEP of less than $10\mu\text{M}$, even those DNA molecules isolated from an *Eleusine* species of grass. The art teaches that EPSPS enzymes from different sources vary widely with respect to their degree of sensitivity to inhibition by glyphosate and that the degree of sensitivity shows no correlation with any genus or species (see Barry *et al*, U.S. Patent 5,627,061, column 2, lines 13-21).

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8. Claims 24 and 25 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims an isolated DNA molecule comprising the promoter region or transit peptide coding region located 5' to a DNA molecule that encodes a naturally occurring glyphosate resistant EPSPS enzyme derived from *Eleusine sp.*

Applicant teaches a naturally occurring mutant DNA isolated from an *Eleusine indica* encoding a glyphosate resistant EPSPS enzyme having a serine substituted for a proline at position 107 in SEQ ID NO: 7.

Applicant does not teach the promoter region or the chloroplast transit peptide coding region of the exemplified *Eleusine indica* isolated DNA.

Applicant's example for identifying and isolating the promoter and/or chloroplast transit peptide of the exemplified *Eleusine indica* encoding a glyphosate resistant EPSPS enzyme of SEQ ID NO: 7 is prophetic (see pages 61-64 of the specification). The instant claims are directed to an isolated DNA molecule from any *Eleusine* species, where Applicant has not even taught one. Hence it would have required undue trial and error experimentation to practice the invention as broadly claimed.

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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10. Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite because positions 102 and 103 are relative to SEQ ID NO: 7, other EPSPS enzymes may or may not have a glycine or a threonine at positions 102 or 103 respectively. Hence, the metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

12. Claims 4 and 5 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lebrun *et al* (US Patent 6,566,587 B1, effective US filing date of 20 January 1998).

Lebrun *et al* disclose a modified DNA molecule encoding a glyphosate resistant EPSPS enzyme having a proline to serine substitution at position 107 relative to

Applicant's SEQ ID NO: 7, and a threonine to isoleucine substitution at position 103 relative to Applicant's SEQ ID NO: 7 (see claim 2). Applicant confirms that the modified DNA molecule disclosed by Lebrun *et al* meets the limitations of the instant claims in having a K_m for phosphoenolpyruvate (PEP) of less than $10\mu\text{M}$ on page 59 of the instant specification. Lebrun *et al* also disclose that a glycine to alanine substitution at position 102 relative to Applicant's SEQ ID NO: 7 can also be made at column 8, last paragraph and column 9, lines 52-67. Hence, Lebrun *et al* have previously disclosed all of the claim limitations.

While the modified DNA disclosed by Lebrun *et al* does not encode a naturally occurring glyphosate resistant EPSPS enzyme, the Examiner interprets "naturally occurring" to be directed to a process steps which does not distinguish the product disclosed by Lebrun *et al* from that of the instant claims. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Conclusion

13. Claims 24 and 25 are free of the prior art which does not teach an isolated DNA molecule encoding an EPSPS enzyme isolated from an *Eleusine sp.*

14. No claims are allowed.

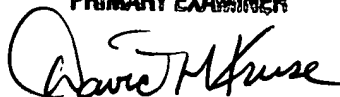
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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
24 February 2006

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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